

MINIMAL ACCESS SURGERY

The expectation is that ten years from now some 70% of surgical operations will be conducted endoscopically. Minimal access surgery (MAS) presents a significant challenge to health care delivery, and the Scottish Office Home and Health Department and Department of Health commissioned an expert working group to consider the implications for patients and the NHS.

Chaired by Professor Alfred Cuschieri of the University of Dundee, the working party reminds us that while it took some 40 years for day-case surgery to become a common feature of health care provision, MAS will need more aggressive consideration.

This they have produced, in a readable and thoughtful booklet available from HMSO. To precis the booklet is not possible. It considers all aspects of the introduction of MAS including management issues, costs, equipment and theatre design, training and guidelines for safe MAS, clinical audit and research. It is clear that there will need to be much new thinking, and health authorities and Trusts should take advantage of the working group's thoughtful words.

As a flavour of what the booklet contains, the conclusions are:-

- MAS is distinctive because of the reduced trauma of access. From this stem all of its advantages.
- MAS is, like day surgery, a short-stay specialty, which requires the same level of specialisation in facilities and staff; the same management efficiency; and corresponding new attitudes and work practices.
- High throughput within designated MAS units is essential for acceptable levels of expertise to be developed and maintained, and to justify high capital investment.
- MAS is estimated in 10 years time to account for 70% of all surgical operations. It has major implications for NHS planning and contracting.
- The overall impact on NHS costs is unlikely to be significant, but there are substantial gains in the quality of treatment and acceptability to patients, and in savings in sickness and other benefits.
- The specialised equipment for MAS requires a high level of efficiency and maintenance. Sterilisation of instruments is a particular concern.
- Safe practice of MAS should be ensured through appropriately regulated training and certification.
- The speed of introduction of MAS presents a major challenge to maintenance of a high quality service in the NHS. Systematic clinical audit, supervised by

a recognised, authoritative group, should be mandatory, to monitor outcomes particularly in the longer term. Guidelines and protocols for good practice should be developed.

- Research is urgently required particularly in relation to development of equipment; biological implications; appropriate use; and outcomes. Appropriate methods of clinical evaluation should be developed.

Research urgently required

This last point in the recommendations is especially important, as the premise is that MAS is going to be the technique of the future in any event. In 1784 Moore wrote "man may wish to publish what he believes will be of public utility, and may think that even the probability of saving severe torture of some of his fellow creatures a stronger reason for doing so immediately, than the risk of offering a defective performance to the Public of delaying it."

Two hundred years later we have a similar dilemma with minimal access interventions. A Luddite stance is unrealistic - the problems lie in the manner in which we assess the techniques, in the timing of the assessment in the development. Done too late we may struggle to stop a harmful technique after widespread investment.

Can it Should it be done?

There are several stages in the process of evaluating new techniques. Two important questions are "Can it be done?" followed by "Should it be done?". Often it seems that if a technique is feasible we assume that it should be done. Evaluating the "Should it be done?" question has to include adverse effect outcomes. There are then two problems for the RCT against the established procedures.

One is the size of the study. If there are serious adverse outcomes with high incidence then these should be identified even in a small study. Serious outcomes with low incidence might be missed even in a moderately large study. These are not new problems, and ever since the thalidomide disaster there has been concern about how best to identify adverse effects when new drugs are introduced.

The second problem is the learning curve for the new procedure. If the RCT against established procedures is organised when the operators are still on the steep part of the learning curve then their operating time may be longer and adverse effect incidence higher than if they were experienced. The pressure is on, however, to subject the new procedure to RCT at the earliest possible stage. Doing the trial

too early may give the wrong result.

We may have to accept that the early RCT against the established procedure is not going to give us the final answer. Just as when new drugs are introduced there are further stages before we can pronounce on the appropriateness of the new procedure. These further stages would require that operators are on the asymptote of the learning curve and that adequate numbers of patients had been studied to detect low incidence adverse effects.

References:

Moore J. A method of preventing or diminishing pain in several operations of surgery. London, Cadell, 1784.
Minimal Access Surgery (December 1993) is available from HMSO, price £6.50.

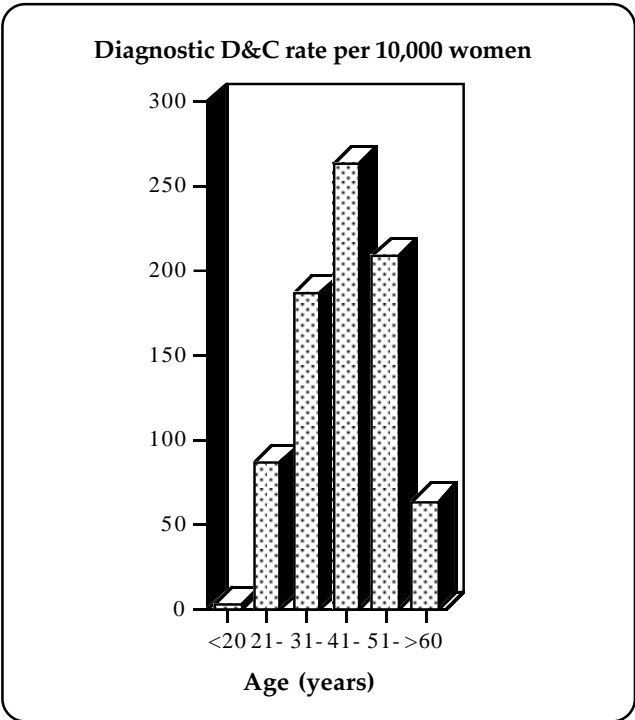
APPROPRIATE D&C

A seminal paper on the appropriate level of dilation and curettage procedures compared in the USA, UK and Oxford Region was published in 1993 by Angela Coulter and her colleagues. The main finding was that the trends for D&C procedures in the UK had been more or less constant between 1977 and 1989, during which period there had been a roughly 9-fold reduction in rates in the USA.

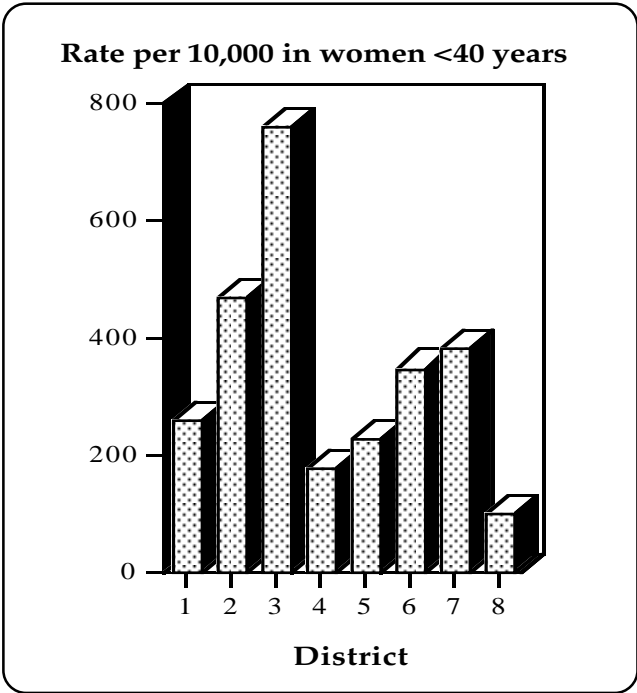
In 1989 the rate in the USA was 10.8 per 10,000 women, compared with 71.1 per 10,000 in England, 65.2 per 10,000 in Scotland and 56.6 per 10,000 in the Oxford Region.

Large differences in rates

In the Oxford Region, the age-specific rates for D&C peaked in the 45-49 age group, but a significant percentage of the total occurred below age 40 years (39% of total).



There was considerable variation between districts for D&C overall, and especially in procedures in women below 40 years; for the latter, the spread in age-standardised rates between the highest and lowest districts was nearly 8-fold.



Is D&C effective?

The procedure was originally thought to have a therapeutic effect on dysfunctional uterine bleeding, but studies have failed to support this. The procedure may be used for diagnostic purposes to exclude endometrial malignancy, but this has been questioned. It is, of course, a useful procedure for removing the products of conception, and the figures quoted refer only to the use of D&C for dysfunctional bleeding.

An age cut-off at 40?

Critics argue that D&C should be restricted to women aged over 40 on the grounds that serious pathology is uncommon in younger women.

Cost implications

The Coulter paper argues that D&C procedures in the Oxford Region cost about £2 million at 1992 prices. Much of this could be saved by reducing the number of diagnostic investigations on young women and by resorting to outpatient procedures for the remainder. D&C involves a general anaesthetic and often a two-day hospital stay: the Audit Commission estimates that up to 86% of patients could be treated as day cases.

Buckinghamshire's GRiP

The Buckinghamshire GRiP initiative began with a review of standardised admission rates for residents of the three localities within the Health Authority for D&C, and the recognition that there were large differences across the Authority, particularly for women under 40 years.

The aim, therefore, was to develop, implement and evaluate a protocol for the treatment of women under 40 with dysfunctional uterine bleeding. This protocol is to become the standard for treatment in Buckinghamshire.

Evaluation is to include an economic evaluation, comparing treatment costs before introduction of the protocol with those afterwards, an evaluation of the effect of the protocol on clinical practice, and a comparison of the change in clinical practice in the county with practice in another DHA where no protocol has been introduced.

How to do it

Essentially, through co-operation, with public health physicians acting as facilitators with gynaecologists and general practitioners. This group devised a draft protocol for discussion with relevant professional groups.

The Buckinghamshire Health Authority will be incorporating the protocol into the 1994/5 contracts with Acute NHS Trusts, and will also be expecting audit of the management of dysfunctional bleeding to be undertaken.

April 1994 saw the introduction of the protocol, and so now it is wait and see time.

Reference:

Coulter et al, British Medical Journal 1993 306: 236-9.

EFFECTIVE REDUCTION IN BENZODIAZEPINE USE IN GENERAL PRACTICE

The size of the problem

Benzodiazepine prescribing in the UK has been falling, but the number of prescriptions is still large. In 1989 there were 21 million prescriptions for hypnotics, sedatives and tranquillisers - the vast majority being benzodiazepines. Of these prescriptions, 9 million prescriptions for sedatives and

12 million prescriptions for hypnotics were issued from family health services at a total cost of some £34 million, with about £27 million of this being for benzodiazepines.

The nature of the problem

GPs have received clear advice about problems associated with prescribing benzodiazepines. Benzodiazepines impair performance (including driving), they affect memory, and have adverse cognitive effects. The British National Formulary states that benzodiazepines should be avoided in elderly people because of risks of ataxia and confusion.

The study

Small studies have shown that a letter from a GP could be as effective as interviews with the GP or a group run by a psychologist in reducing benzodiazepine use. This has now been tested in a randomised controlled trial.

Patients taking benzodiazepines (more than 6 months) were identified from the lists of 10 GPs from three group practices - *all of which had a policy of trying to reduce benzodiazepine prescribing in existence*. 209 patients were identified, with ages from 34 to 102 years (median 71); the ratio of women to men was 4:1, and the median duration of benzodiazepine use was 15 years (1-29 years). Patients taking benzodiazepines for certain defined conditions (like current psychosis or dementia) were not included.

These patients were randomly allocated to one of three groups:-

- No intervention.
- Received a letter from the GP asking them to try to reduce or stop their medication, and explaining how to do this.
- Received the same letter, together with four information sheets at monthly intervals.

Patients' use of benzodiazepines was monitored for one year before the intervention, and for six months afterwards, by analysis of repeat prescriptions.

And the results

Patients in the two intervention groups reduced their consumption of benzodiazepines by at least 30% compared with

	Percent of Patients	
Group	No Prescriptions	50% Reduction in Prescriptions
Control	6	16
Letter only	23	37
Letter and information	13	49

the control group, which was highly statistically significant. There was no difference between the two interventions, of letter only or letter plus follow-up information.

Combining the two intervention groups, about a fifth of patients stopped taking benzodiazepines (compared with 6% in the control group) and over 40% reduced their consumption by half (more than twice that seen in the control group).

It has to be recognised that these results were obtained in practices which had positive policies to reduce benzodiazepine prescribing.

Cost effective?

The letter patients received is reproduced in the original article, and on average each GP sent out 20 letters - not overly demanding or expensive.

Nationally the effect could be savings of over £4 million on the drugs budget at 1989 prices. This about £100,000 per million population. There may well be fewer confused elderly patients around, with a positive effect on general levels of health.

Reference:

Cormack et al, British Journal of General Practice
1994 44: 5-8.

Questions to be Answered

- Q: What need is met by this?
A: Reduction in consumption of benzodiazepines, mainly by elderly patients.
- Q: Is quality increased?
A: Yes - there will be fewer unwanted effects in patients who reduce their use of benzodiazepines.
- Q: What is the cost of this intervention?
A: Effectively nothing.
- Q: Can cost savings be made?
A: Yes - savings of at least £100,000 per million population could be expected if this process was followed by GPs nationally.

Advice to Health Authorities and GPFHs

- 1 Will increase quality and effectiveness.
- 2 Will decrease total cost of care.

THYROXINE - A SUITABLE CASE FOR TREATMENT

One of the most useful developments in laboratory diagnostics in recent years has been the advent of new high-sensitivity assays for thyroid stimulating hormone (TSH). It is an important test for many aspects of pituitary and thyroid function, but it is becoming much more useful as the sensitive assays can now define a reference (or normal) range of about 0.4 to 4.0 mU/L. Values below normal can now be measured (in some systems down to 0.002 mU/L), whereas previous methods could not discriminate values below normal.

TSH and thyroxine treatment

TSH measurement is useful in measuring whether patients who receive thyroxine for hypothyroidism are getting the right dose; TSH is elevated in untreated patients, but falls to the normal range in a few weeks of treatment with an appropriate dose. That is the theory, but until recently, this could not be tested in practice.

Now, however, a group in Birmingham has reviewed the status of treatment of patients with hypothyroidism in general practice in England. They examined four West Midlands general practices who had 18,944 patients registered. Of these, 146 (0.8%) were being prescribed thyroxine, 134 for primary hypothyroidism, and the remainder for other appropriate reasons, such as hypopituitarism and thyroid cancer.

48% of hypothyroid patients get the wrong dose

Or, of course, they may not take it if given the right dose. In any event, as judged by the serum TSH, 27% were being undertreated as they had high TSH levels, and 21% were being overtreated, as they had low TSH values. The proportion of undertreated patients was high in those with the lowest doses of thyroxine.

Is this a bad thing?

The truth is that we probably don't know the full effects of under or over treatment, as up till now there have of necessity been no studies. Half of those undertreated in this survey (about 13% of all patients with treated primary hypothyroidism) had TSH values above 10 mU/L; it is unlikely that all the symptoms of hypothyroidism would be completely eliminated in these patients. Undertreatment may be associated with increased long-term risks of heart disease, but this is not quantifiable. Overtreatment is still more difficult - but osteoporosis may be a potential problem.

What of the future

Methods for measuring TSH accurately within and below the normal range are now commonly available and should

Thyroxine ($\mu\text{g/day}$)	Number	Median TSH (mU/L)	Percent with high TSH
<100	9	4.5	47
100	1	2.4	}
100-200	19	1.2	} 21
>200	8	1.8	}

be accessible to Trusts and GPs. Regular biochemical monitoring for TSH (say annually) of patients with primary hypothyroidism treated with thyroxine should be useful for encouraging compliance. Further research is indicated to determine the benefits that might accrue from maintaining appropriate therapy in this group of patients.

Reference:

Parle et al, British Journal of General Practice 1993 43: 107-9.

Questions to be Answered

- Q: What need is met by this test?
A: TSH is used in the diagnosis of thyroid disease; new assays with high sensitivity also allow it to be used to monitor the effectiveness of thyroid replacement.
- Q: What happens at present?
A: Surveys show that patients on thyroxine have TSH checked irregularly - and that 48% are taking the wrong dose. This is 0.4% of the population.
- Q: Is quality improved?
A: Not proven for the whole thyroxine replacement population, though it is certain that quality will be improved for a significant percentage of these patients.
- Q: What is the cost?
A: Most laboratories perform thousands of tests a year. There is a need to ensure that they have adequate sensitivity, but the incremental cost of testing thyroxine replacement patients annually is minimal.
- Q: Can cost savings be made?
A: Probably not in any volume.

Advice to Health Authorities and GPFHs

- 1 Will increase quality and effectiveness
- 2 Cost neutral
- 3 Worth considering including need for high sensitivity TSH tests in specifications to laboratories

OSTEOARTHRITIS OF THE KNEE - KEEPING IT TAPED!

Osteoarthritis of the knee is one of the commonest causes of chronic pain and disability in the community, and especially the elderly. Treatment is usually with physiotherapy and use of analgesic and anti-inflammatory drugs, measures which are expensive and carry some dangers for patients.

A really simple way of doing something that is effective, is simple, is cheap, and is under the control of the patient has been reported from Bristol.

Randomised controlled trial

Fourteen patients attending a rheumatology clinic had radiographic evidence of osteoarthritis in the patellofemoral compartment. All had anterior knee pain, difficulty with walking and had trouble with stairs and steps.

Patients had their knees taped: taping was:-

- Neutral - with the tape applied directly over the front of the patella, without any pressure.
- Medial - with the tape pulling the patella to the medial side of the knee.
- Lateral - with the tape pulling the patella to the lateral side of the knee.

Patients had their knees taped for four days, and crossed over to all three methods of taping with a three day interval. The order of the three treatments was randomised. Scores for the overall pain on each of the four days were recorded for each treatment.

The results

The medial tape resulted in a 25% reduction in knee pain compared with neutral or lateral taping. It was significantly better than the other two methods.

The implications

Patellofemoral joint osteoarthritis is common, causing con-

siderable pain and disability and representing a serious healthcare problem. The Bristol group report that patients were able to apply their own tape after minimal instruction, providing them with a low cost, easy means of treatment under their own control.

Reference:

Cushnaghan et al. British Medical Journal 1994 308: 753-5.

Questions to be Answered

- Q: What need is met by this intervention?
A: Significant reductions in pain with patients with arthritic knees.
- Q: What happens at present?
A: Patients have physiotherapy and/or are treated with analgesics or anti-inflammatory drugs.
- Q: Is quality improved?
A: Yes - pain is reduced and patients should have more control over their own treatment.
- Q: What are the cost implications?
A: Should reduce costs in drugs budgets and may reduce pressure on physiotherapy services. □ Cost benefits are unquantified.
- Q: Is more information needed?
A: Yes: this study examined 14 patients only. Longer term studies with more patients are needed to define efficacy, safety and cost-effectiveness.

Advice to Health Authorities and GPFHs

- 1 Will increase quality or effectiveness
- 2 Likely to reduce costs

THE ORDER OF THE BATH

Medicine often deals with complex and technologically advanced subjects, but its the simple things that are most often important to patients. Three cheers, then, for a down to earth piece from Leeds in a recent BMJ.

Survey

Over a one week period, a senior house officer surveyed all inpatients in eight wards, and all those attending the geriatric day hospital at St James's University Hospital, a total of 129 inpatients and 18 day patients. The patients were asked if they had ever been unable to get out of their bath at home.

Results

Twenty one patients (14%) said they had been unable to get out of the bath at some time, and though most were stuck in their bath for less than an hour, three were stuck for 1-4 hours, and two were stuck overnight. Two were stuck more than once.

Again, most suffered no trauma, but two suffered bruising, one pressure sores and burns, and one had a myocardial infarction.

The reasons for being stuck were split almost equally between a physical disability, and the bath and its environment: lack of bath aids, such as grab rails, was a major factor in preventing people getting themselves out. Only a few were able to free themselves unaided, most needing help, and one needing an ambulance crew.

Conclusions

In this simple survey, one in seven elderly patients aged 70 to 89 years had been stuck in a bath at home. Given that the UK has a large and growing elderly population, this is a problem which needs evaluation. It is a problem easily solved, in most cases, even for people living on their own. Although it is not a medical problem in itself, it could impact on the health of elderly people, and the use of services.

What to do?

It may be that this survey represents an atypical group of patients. They are selected, in that they *are* patients. Do bath accidents represent a real threat to the elderly living alone, and if so what can be done about it?

It seems that there are questions to be answered here, which touch on the borderline of health and social services. Bath aids (like hand grips, shower stools and the like) are readily available from a number of sources, are relatively inexpensive and not difficult to fit or use.

What is needed here is more information, and perhaps a study looking at the effectiveness of bath aids in preventing accidents in the elderly.

Reference:

Gooptu & Mulley, British Medical Journal 1994 308: 762.

MANAGEMENT OF SUBFERTILITY

The third Effective Health Care Bulletin from the University of Leeds published in 1992 covered this interesting and important topic. This is a thorough but highly readable document that richly repays an hour in an armchair.

The size of the problem

A health authority with a population of 250,000 will have 46,000 women aged 20-44 years, with about 230 (0.5%) new

consultant referrals each year. The proportion of women of childbearing age experiencing subfertility is 9-14%.

A useful definition of subfertility is failure to conceive after two years during which there has been intercourse and no use of contraception. After one year 80-90% of couples attempting to conceive are successful, rising to about 95% after two years.

Causes of subfertility

There is no explanation for infertility in 30% of couples. In about 19% there is a male factor (azoospermia for instance), in 27% there is ovulatory failure in the woman, in 14% tubal damage exists, and endometriosis or other causes make up about 5% each.

Does treatment work?

To some extent this depends on how the question is framed. Firstly, patients (couples) undergoing treatment may experience spontaneous pregnancies; measures of effectiveness should take this into account. Again, in determining a reproductive outcome there are several criteria which have been used as measures; these include biochemical evidence of pregnancy, a clinical pregnancy, an ongoing pregnancy, births and maternities. In general, the numbers fall as one proceeds along this list; maternities, that is the proportion of couples who have a child, is probably the hardest outcome measure.

The Effectiveness Bulletin does an excellent job of introducing the reader to the complexities involved in evaluating effectiveness. In addition, it has a number of appendices listing many reports, studies, reviews and RCTs of different methods of treatment with main outcomes. It makes sobering reading to realise that the number of successful maternities is really quite low for many techniques (although the latest data reported are from about 1990/91).

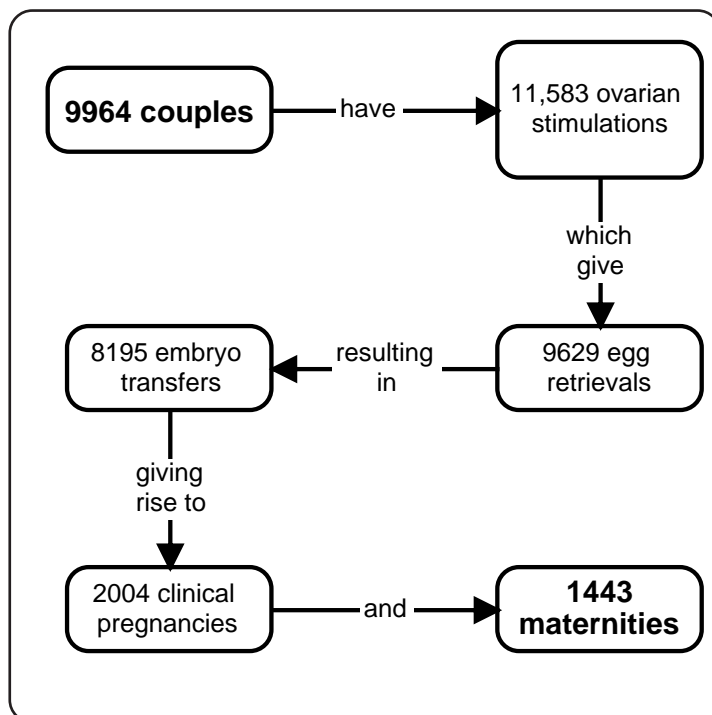
Individual sections on male subfertility, and female problems of tubal factors, ovulatory dysfunction and endometriosis, as well as unexplained subfertility are all reviewed as to the results of studies, and the methods which are most effective (if that is known).

Assisted conception methods

The most commonly practised technique is IVF-ET (In-vitro fertilisation with embryo transfer). Eggs and sperm are collected, mixed in the laboratory and incubated for 2-3 days until fertilisation is achieved, and when achieved, the fertilised eggs are injected into the uterus.

The Bulletin gives a number of Tables comparing the pregnancy and maternity rates for IVF-ET and other techniques, and for different causes of subfertility, but the success rate of 145 of couples having a second child seems to be typical.

The average reproductive experience of all UK patients receiving IVF-ET in 1990 was followed, and the results have been collated for the 'national experience'.



So 14% of couples entering the programmes have a baby.

And their problems

- Between 1978 and 1987 24% of births after IVF-ET were preterm, compared with 6% for natural conceptions.
- Some 26% of births were multiple births (22% twins, 4% triplets), compared with the natural rate of 1%.
- Low birth weight is a problem: 32% weighed less than 2500 g, and 7% weighed less than 1500 g. This compares with 7% and 1% respectively for all births.
- There was a higher rate of perinatal mortality of 19 / 1000 pregnancies and 26 / 1000 live births with assisted conception, compared with 8 / 1000 pregnancies and 16 / 1000 live births for natural conceptions.
- Congenital malformations are not a problem.

Cost effective purchasing

There is a really good discussion about the issues involved with cost effective purchasing. Based on a hypothetical DHA with a population of 250,000, it costs out the typical programme of subfertility treatments expected. The costing also adds in other charges, to come up with an overall figure of £880,000 (1992/93 prices), though the Bulletin goes on to explain why funding a comprehensive service should be less costly at about £750,000.

There are also a number of helpful and considered guidelines on organisation and management of services.

HOSPITAL LOSS-LEAD PRESCRIBING

- REALITY OR MYTH?

Background

Many people believe that hospital prescribing ‘drives’ prescribing in primary care. One driver is that the GP repeats the hospital prescription as reflecting best opinion, the so-called “halo effect”; the other is financial. Hospitals are thought to buy expensive drugs cheaply and force up community prescribing budgets, so-called “loss leaders”. What is the reality?

Shopping basket: top 100 drugs by cost

PACT level 3 data for the Oxford Region (4th quarter 1993) was manually trawled to identify the top 100 drugs by total expenditure for the region. These drugs were then costed to provide the community cost, first by drug tariff and then by wholesaler price list for items not in the tariff. The true hospital price was then determined (cost plus VAT) from contract files, or pharmacy computer database. Total basket cost was obtained from cost of similar packs (ie comparing like with like).

The cost to the community pharmacist of this ‘basket’ of 100 drugs was £1665; the cost to the hospital pharmacist was £1553. The difference was 7%.

The actual value of the 100 drugs was £5,579,866 which is 55% of the total expenditure for this quarter. When the differences were broken down the following categories were identified:

This means, for example, that 14 drugs cost the hospital between 50 and 75% of the FHSA price, and accounted for 12% of the FHSA drugs bill. The five drugs which were 75% or more cheaper in hospital than in the community (i.e. potential loss leaders) were diclofenac 25 mg tablets (ranked no. 3), co-amilofruse tablets (13), azathioprine 50 mg tablets (58), co-amilozide tablets (71) and fenbufen 300 mg tabs (73).

Among the top 100 drugs prescribed by GPs there are very few drugs which are purchased cheaply by hospital and used to treat large numbers of patients. Apart from co-amilofruse, now discontinued in Oxfordshire hospitals, and possibly ranitidine, there is insufficient evidence to lay the blame for high GP prescribing costs on hospital loss-lead prescribing.

Philip Wiffen & Dennis Lauder

Ratio of hospital to FHSA cost	No of Drugs	% of FHSA drugs bill
<0.25	5	6%
0.25 - 0.49	17	19%
0.5 - 0.7	14	12%
0.75 - 1	19	14%
>1	45	49%